Federal E-cigarette Regulation
Explained

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From the Beginning

- FDA's Deeming Rule on tobacco products
  - In 2009, FDA acquired regulatory authority over tobacco products
- FDA's primary role was to ensure that the benefit to public health out-weighed the harm (medication)
- Commercial tobacco products have no beneficial use
  - In this case the FDA role is to protect consumers from unnecessary harm from new tobacco products and that those products are in compliance with statutory requirements

May 10, 2016 Update

- Additional products added/defined:
  - E-cigarettes
  - Cigars
  - Waterpipe tobacco
  - Future products made or derived from tobacco
- New Products could not be marketed without FDA approval
  - New products: any tobacco product (including test markets) that were not commercially marketed in the USA as of Feb. 15, 2007.
  - This includes products that had any modifications made after Feb. 15, 2007

Grandfathered Products

- Products on the market as of Feb. 15, 2007
  - Do not require an application
  - There is a voluntary grandfather determination request

- Grandfather Request Components
  - A description of the product, including name it was marketed under prior to Feb. 15, 2007, and characteristics that uniquely Identify the product
  - A statement that the product was commercially marketed, not just test market, in the USA as of Feb. 15, 2007
  - Dated evidence that shows the product was commercially marketed in the USA as of Feb. 15, 2007

Types of Pathways

Three Types:

- Substantial Equivalence (SE)
- Request Exemption from Substantial Equivalence (EX REQ)
- Premarket Tobacco Product Application (PMTA)

Substantial Equivalence

- A new tobacco product may be found “substantially equivalent,” to a “predicate” product by demonstrating the product has the same characteristics as that predicate product, or by demonstrating that the new product does not raise different questions of public health than the predicate product

- Likely pathway for Cigars, Pipe Tobacco, and Hookah Tobacco

Request Exemption from Substantial Equivalence

- A tobacco product that is modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive may be considered for exemption from demonstrating substantial equivalence

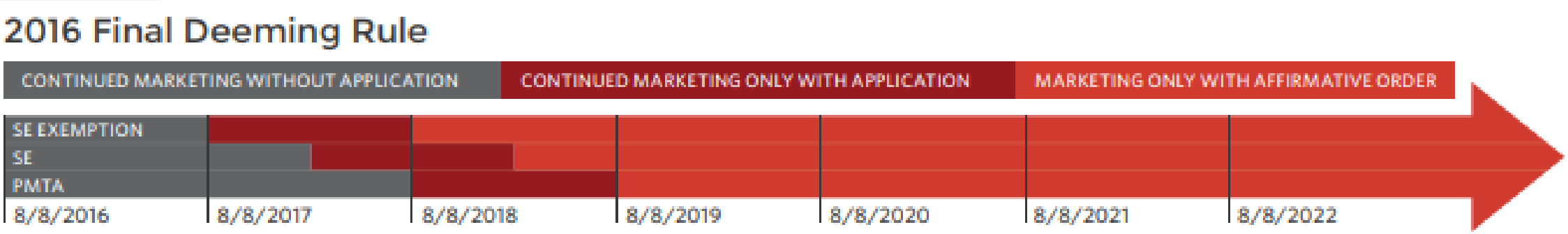
- Likely pathway for Cigars, Pipe Tobacco, and Hookah Tobacco

Premarket Tobacco Product Application

- A premarket tobacco product application may be submitted when seeking marketing authorization for any new tobacco product

- Most likely path for Electronic Nicotine Delivery Systems (ENDS), including e-cigarettes and e-liquids

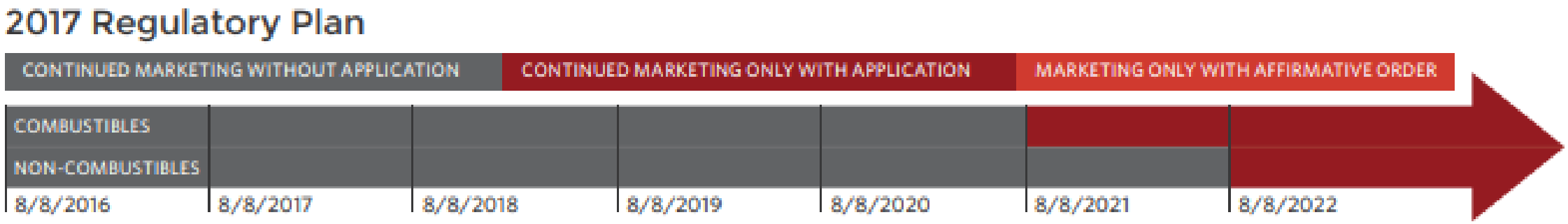
Original timeline



For products on the market Aug. 8, 2016 FDA used staggering deadlines for manufacturers to submit applications per the pathway chosen

https://www.publichealthlawcenter.org/sites/default/files/resources/FDA-Gatekeeping-Authority-for-E-Cigarettes.pdf

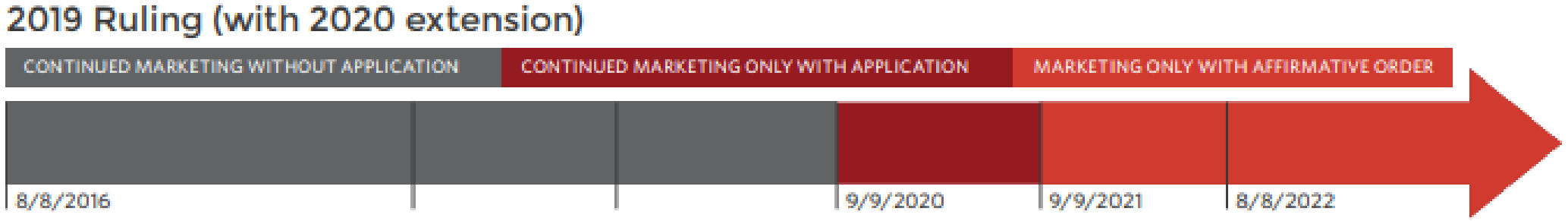
2017 Updated Timeline



July 28, 2017, a new regulatory plan was announced. This extended the original dates by 4 years.

https://www.publichealthlawcenter.org/sites/default/files/resources/FDA-Gatekeeping-Authority-for-E-Cigarettes.pdf

Current Timeline (2019)



May 15, 2019: a Judge Grimm ruled in favor of the public health groups finding the FDA had failed to ensure that new tobacco products underwent the statutorily mandated premarket review process

July 12, 2019: Judge Grimm issued an order requiring new products file marketing applications by May 12, 2020

https://www.publichealthlawcenter.org/sites/default/files/resources/FDA-Gatekeeping-Authority-for-E-Cigarettes.pdf

What happens now?

- Three Phases
- FDA may contact the applicant at several points during the review process during any of the phases
- FDA website has a variety of resources for each application type and required information to include per application type as well

https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=landingpage&utm_campaign=CTP%20News%3A%20Application%20Tips%20Email%206%20-%209320

What happens now?

- FDA will start to prioritize enforcement against any ENDS product that continues to be sold without an application having been received
- FDA plans to be transparent in regards to status of the submissions and provide regular updates to the public
- As of Aug. 31, 2020 no ENDS products received marketing authorization from FDA and FDA has not issued a grandfathered status determination for an ENDS product.

What happens now?

- Since 2009, FDA has received
  - Over 600 PMTAs
  - Over 7,700 SEs
  - Over 800 EX REQs

  *FDA has closed a large majority of these applications
- FDA does plan to make a publicly available a list of the deemed new tobacco products that are subject to the Sept. 9, deadline
  - They do need to first make sure doing so does not violate any federal disclosure laws and regulations

Resources

- https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders
- https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline
- https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=landingpage&utm_campaign=CTP%20News%3A%20Application%20Tips%20Email%206%20-%209320
- https://www.publichealthlawcenter.org/sites/default/files/resources/FDA-Gatekeeping-Authority-for-E-Cigarettes.pdf

Flavors Regulation and Enforcement

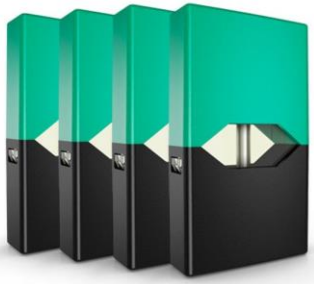
Jan. 2, 2020:Enforcement of flavored cartridge-based e-cigarettes

“The United States has never seen an epidemic of substance use arise as quickly as our current epidemic of youth use of e-cigarettes. HHS is taking a comprehensive, aggressive approach to enforcing the law passed by Congress, under which no e-cigarettes are currently on the market legally,” said HHS Secretary Alex Azar. “By prioritizing enforcement against the products that are most widely used by children, our action today seeks to strike the right public health balance by maintaining e-cigarettes as a potential off-ramp for adults using combustible tobacco while ensuring these products don’t provide an on-ramp to nicotine addiction for our youth. We will not stand idly by as this crisis among America’s youth grows and evolves, and we will continue monitoring the situation and take further actions as necessary.”

Enforcement took effect

- On Feb. 6, 2020 FDA began prioritizing enforcement against certain illegally marketed ENDS products by focusing on groups of products that do not have premarket authorization:
  - Any flavored, cartridge-based ENDS product (other than a tobacco or menthol flavored ENDS product)
  - All other ENDS products for which the manufacturer has failed to take (or is Failing to take) adequate measures to prevent minors' access; and
  - Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors

Flavor ban update



WARNING: THIS PRODUCT CONTAINS NICOTINE.
NICOTINE IS AN ADDICTIVE CHEMICAL.

INDIANA FAMILY & SOCIAL SERVICES ADMINISTRATION
FSSA

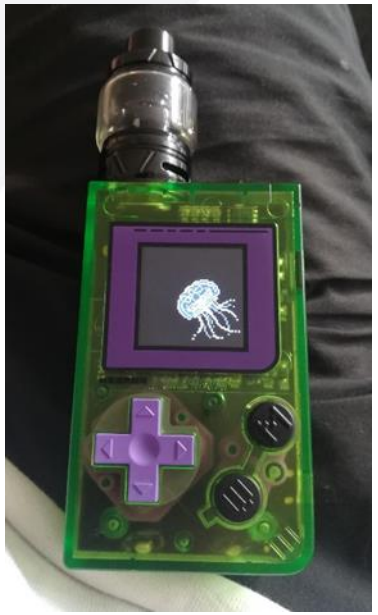
Enforcement took effect

- March 10, 2020:
  - FDA issued 22 warning letters to brick-and-mortar e-cigarette product retailers and manufacturers

- April 27, 2020:
  - FDA issued 10 warning letters to retailers and manufacturers who sell, manufacture and/or import ENDS products targeted to youth or likely to promote youth use

https://www.fda.gov/tobacco-products/ctp-newsroom/enforcement-actions-against-illegally-marketed-tobacco-products

Types of Products addressed in warning letters



Picture is Provided by the Man

Enforcement took effect

- July 20, 2020:
  - FDA issued another 10 warning letters to companies notifying them to remove their flavored disposable and youth appealing e-liquids

https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth

Lung Injuries

What we know

- Cases have been declining since Sept. 2019
  - As of Feb. 18, 2020, 2,807 cases have been reported, 68 were deaths
- FDA has received 1,090 samples connected to patients
  - 843 have been tested
  - 511 of those contained THC
    - 50% had vitamin E acetate with concentration of 23%-88%
- CDC and FDA are still collecting any information and new cases of lung injury/illness related to vaping

https://www.fda.gov/news-events/public-health-focus/lung-injuries-associated-use-vaping-products

Now what?

- Indiana's last report
  - As of March 13, 2020, 60 confirmed, 68 probable and 6 deaths
- Vitamin E Acetate and THC containing products tend to be very common among those with EVALI, however there is not enough evidence to rule out other possible chemicals
- FDA encourages continued reporting to local Health Departments
  - FDA also have a safety portal where you can report any health related issues from a tobacco product

https://www.in.gov/isdh/28337.htm
https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=542c5705-b35b-420f-877a-fd8e425ecf9c

Where to report violations

Reporting violations

- Possible violations to report
  - Sales to minors
  - Flavored cigarette sales
  - Illegal marketing and advertising
  - Distribution of free samples of tobacco products
  - Placement of cigarette or smokeless tobacco product vending machines in prohibited areas
  - Sale of cigarette in packages of less than 20
- Ways to report
  - Online: https://www.accessdata.fda.gov/scripts/ptvr/index.cfm
  - Call the Tobacco Center at 1-877-CTP-1373
  - Email: CTPCompliance@FDA.hhs.gov
  - Print and Mail

https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation

Other Resources

Resources

- FDA Webinars: https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars
- Federal Tobacco 21: https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21
- FDA Compliance/Enforcement: https://www.fda.gov/tobacco-products/compliance-enforcement-training
- Public Health Law Center: FDA Tobacco Action Center, https://www.publichealthlawcenter.org/topics/tobacco-control/fda-tobacco-action-center
- Food, Drug, and Law Institute: https://www.fdli.org/

Thank you

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